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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,435	11/12/2003	David E. Lanar	003/285/SAP	7145

7590 06/16/2006

ATTN: MCMR-JA (Ms. Elizabeth Arwine-PATTENT ATTY)
U.S. Army Medical Research and Material Command
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER	
VOGEL, NANCY S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,435	LANAR ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-92* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-92* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, and 39-44, 46, 47, 49-64, drawn to a recombinant LSA-NRC polypeptide comprising at least one LSA-1 epitope, and immunogenic carrier comprising said polypeptide, and kits comprising said polypeptide, classified in class 530, subclass 350.

II. Claims 11-23, drawn to a recombinant vector comprising DNA sequence encoding a LSA-NRC polypeptide comprising at least one LSA-1 epitope, and host cell comprising said vector, classified in class 435, subclasses 320.1 and 252.33.

III.. Claims 24-26, drawn to a method for producing and purifying recombinant P. falciparum LSA-NRC polypeptide comprising growing a host cell containing a vector expressing P. falciparum LSA-NRC polypeptide, classified in class 435, subclass 69.3.

IV. Claims 27-36 and 38 drawn to an antibody produced against a recombinant LSA-NRC polypeptide comprising at least one LSA-1 epitope, and a kit comprising said antibody, classified in class 424, subclass 139.1.

V. Claim 37, drawn to a method for in vitro diagnosis or detection malaria antigen in a biological sample comprising contacting the sample with a LSA-NRC specific antibody, classified in class 435, subclass 7.22

VI. Claim 45, drawn to a method for in vitro diagnosis of malaria antibodies in a biological sample comprising contacting said sample with a composition comprising a LSA-NRC polypeptide comprising at least one LSA-1 epitope, classified in class 435 subclass 7.22.

VII. Claim 48, drawn to a method for in vitro monitoring malaria infection or prognosing the response to treatment of patients suffering from malaria infection comprising incubating a biological sample with an LSA-NRC protein removing unbound components and calculating the anti-LSA-1 titers present in the sample classified in class 435, subclass 7.22.

VIII. Claims 65-90, drawn to a method of inducing an immune or protective response in a mammal comprising administering a composition comprising a LSA-NRC, classified in class 424, subclass 191.1.

IX. Claims 91 and 92, drawn to a multivalent vaccine comprising LSA-NRC polypeptides from more than one strain of P. falciparum chosen from the group consisting of 3D7, FVO, T9/96, NF54 and camp, classified in class 424, subclass 191.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process, such as in vitro synthesis by the Merrifield method.

Inventions of Group I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as in a method of immunization when combined with a suitable carrier.

Inventions of Group I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as in a method of immunization when combined with a suitable carrier.

Inventions of Group I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as in a method of in vitro diagnosis of malaria antibodies in a biological sample.

Inventions of Group IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as a probe in a Western hybridization procedure.

Inventions of Groups III, V, VI, VII, and VIII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups III, V, VI, VII and VIII comprise steps which are not required for or present in the methods of the other groups: growing a host cell comprising a vector expressing a LSA-NRC polypeptide (III); contacting a biological sample with an antibody (V); detecting the presence of immune complexes visually or mechanically (VI); removing unbound components (VII); administering a composition comprising a LSA-NRC to a mammal (VIII) . The end result of the methods are different: the production of a polypeptide (III); the detection of an antigen in a biological sample (V); the diagnosis of malaria antibodies in a biological sample (VI); the determination of anti-LSA-1 titers present in a sample (VII); a mammal with an immune response (VIII). Thus, the operation, function and effects of these different methods are different and distinct from

each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The products of Group I, II, IV, and IX, are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

Except for the specific relationships described above, the invention of Groups I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different products of Groups I, II, IV, IX are not used in or made by the methods of Groups III, V, VI, VII, VIII.

Groups I-IX are each comprised of multiple inventions which are the products or methods drawn to different, distinct, and independent sequences, drawn to different proteins, and vectors comprising different DNA sequences encoding said sequences, a methods of making and using said proteins, which do not render obvious each other and thus are independent and distinct. Applicants must also elect a single invention which is the product or method drawn to one specific sequence to which the claims will be restricted. This is not an election of species because the sequences are independent and distinct inventions and thus the products or methods drawn to different

independent and distinct sequences are independent and distinct inventions from each other. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application. Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to independent or distinct types of products and methods, followed by an election of a single invention drawn to one sequence within the elected multi-invention group, was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each separate invention drawn to each separate sequence which would require a much longer communication.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further more, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NANCY VOGEL
PRIMARY EXAMINER

NV
6/2/06